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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/074,687 | 02/11/2002 | Feng-Jing Chen | 6200-0004.20 | 9747 |

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THORPE NORTH & WESTERN, LLP.
8180 SOUTH 700 EAST, SUITE 200
SANDY, UT 84070

EXAMINER

CHANNAVAJALA, LAKSHMI SARADA

| | |
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| ART UNIT | PAPER NUMBER |
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1615

DATE MAILED: 03/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|---|------------------------------------|--|
| Office Action Summary | Application No. 10/074,687 | Applicant(s) CHEN ET AL. | |
| | Examiner Lakshmi S. Channavajjala | Art Unit 1615 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 November 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-145 is/are pending in the application.
- 4a) Of the above claim(s) 3,4,18-23,38,67-71,88-93,108 and 134-145 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,5-17,24-37,39-66,72-87,94-107 and 109-133 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1615

DETAILED ACTION

Receipt of response dated 11-25-05 is acknowledged.

Claims 1-145 are pending in the instant application. Claims 3, 4, 18-23, 38, 67-71, 88-93, 108 and 134-145 have been withdrawn as being non-elected.

Claims 1, 2, 5-17, 24-37, 39-66, 72-87, 94-107 and 109-133 have been examined.

Response to Arguments

Applicant's arguments 11-09-05 have been fully considered. The previous rejection has been withdrawn and the following is a new rejection:

Claim Rejections - 35 USC § 103

Claims 1, 2, 5-17, 24-37, 39-66, 72-87, 94-107 and 109-133 are rejected under 35 USC 103(a) as being unpatentable over US 6,096,338 to Lacy et al (Lacy) itself or Lacy in view of US 4,897,269 to Mezei.

Instant claims are directed to a pharmaceutical composition comprising a first and second fraction of active agent, wherein the first fraction comprising at least about 5% to 80% of solid particles the active agent in a suspended form and the second fraction comprising about 20% to 95% in a solubilized form in a vehicle selected from a hydrophilic surfactant, lipophilic surfactant, a triglyceride or a solubilizer.

Art Unit: 1615

Lacy teaches delivery systems for hydrophobic drugs comprising a carrier for the drugs and pharmaceutical carriers based on the carrier. Lacy teaches various carriers for hydrophobic drugs that include digestible oil, a hydrophilic surfactant and a lipophilic surfactant (col. 4, lines 1-15). Lacy teaches that the carrier system is suitable for improving the bioavailability of a drug that is dispersed as well as dissolved in a digestible oil, where the hydrophilic surfactant inhibits the lipolysis of the oil and the lipophilic surfactant capable of at least substantially reducing said inhibitory effect of lipolysis (col. 4, lines 21-30). More specifically, Lacy teaches the surfactants (col. 4, lines 52 through col.8, lines 49) and the digestible oils (col. 9, lines 1-67) that are also described in the instant invention. Lacy also teaches all the drugs or classes of drugs that are also described and claimed in the instant application (col. 11-13). With respect to the claimed dosage forms, Lacy teaches solid, liquid or semi-solid compositions such as tablets, capsules, oral liquids etc (col. 14). Lacy also teaches the excipients, additives, and stabilizers etc., claimed in the instant application (examples).

Lacy differs from the instant invention in the absence of both solubilized and suspended drug fragment in the same composition. However, Lacy teaches that that the system is suitable for both types of drugs (solubilized and suspended) forms. Further, Lacy teaches the preparation of the composition in col. 14, lines 61 through col. 15, which involves the same steps as that described in the instant examples. Moreover, paragraph 0269 of the specification describes that the isotretinoin of example 4, prepared by the method described in paragraph 0262, contains at least 20% solubilized isotretinoin. When compared

Art Unit: 1615

with a comparative composition, Accutane, applicants state that the composition of example was significantly better than Accutane (wherein less than 10% is solubilized). However, examiner notes that the preparation of the composition described by Lacy (col. 14, lines 61 through col. 15, lines 14) is the same as that described in examples 4 (which is admittedly same as in example 1, paragraph 0262) . Thus, absent evidence to the contrary, the process of Lacy also results in a hydrophobic drug composition that contains both solubilized as well as suspended drug in the same composition.

Further, instant dependent claims recite specific amounts of active agents, vehicle compounds, and release rates of drugs from the first and second fractions, which are not described by Lacy. However, Lacy suggests a drug formulation for both types of drug forms (suspended and solubilized) and accordingly it would have been obvious for one of an ordinary skill in the art to optimize the amount of drugs, vehicles and excipients in the drug delivery compositions of Lacy depending on the drug, excipients and the type of dosage form desired so as to achieve the desired release rate and bioavailability would have been obvious for one of an ordinary skill in the art.

Alternatively, Mezei teaches a method of administering a slightly water-soluble drug, wherein the drug composition comprises both saturated solution and a biologically active solid form of the same active agent (abstract, col. 4, lines 5-40). Mezei teaches that such a multicomponent system is suitable for various routes of drug administration and also provides a unique biopharmaceutical system, where the absorption and disposition of the active

Art Unit: 1615

agent can be controlled. Accordingly, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to use both a solid particulate and a solubilized form of an active agent in a drug delivery composition because Mezei suggests that the difference in the rates of absorption, distribution and metabolism of the different forms (solid or soluble) of the same active agent results in a differential and thus a controlled release of the active agent (col. 5, lines 10-25; col. 7, lines 7-30). Further, optimizing the amount of drug and particle size of a drug would have been obvious for one of an ordinary skill in the art depending on the drug employed, carrier system selected, type of dosage form prepared and the release pattern desired, as suggested by Lacy.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 9.00 AM - 6.30 PM

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1615

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Lakshmi S Channavajjala
Examiner
Art Unit 1615

February 21, 2006